

Application No. 10/050,664
Amendment "A" dated April 4, 2005
Reply to Office Action mailed December 28, 2004

REMARKS/ARGUMENTS

Applicants and Applicants' attorney express appreciation to the Examiner and his supervisor for the courtesies extended during the recent interview held on March 29, 2005. Reconsideration and allowance of the above-identified application are now respectfully requested. Claims 1-27 are pending, wherein claims 1 and 20-25 have been amended.

As discussed during the examiner interview, a major problem with applying a disinfecting composition such as sodium hypochlorite to a tooth is the difficulty in confining the composition to the tooth to which it is applied. Failure to properly confine a sodium hypochlorite or other disinfecting composition can be harmful or irritating to surrounding oral tissues. Application, page 4, lines 8-11. One attempt to keep a disinfecting composition from flowing onto surrounding oral tissue involves the use of a rubber dam barrier to isolate the tooth, which is not always effective. Application, page 4, lines 11-14.

The present invention provides a solution to this problem by providing a method in which a viscous disinfecting composition able to adhere to the walls of a root canal is applied to the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal. Application, page 5, lines 2-4. The use of a viscous disinfecting composition helps the composition "to be applied in a more controlled manner than is possible using existing low viscosity disinfecting compositions". Application, page 5, lines 15-17.

The Office Action rejects the claims over Hahn (US 6,139,320), either alone or in combination with Clay (US 6,413,499), Lee et al. (US 2002/0192627), or Nance (US 6,638,064). Preliminarily, Applicants wish to point out that neither *Clay* nor *Lee* teach or suggest a method in which a disinfecting composition is placed into a root canal in order to disinfect and clean the

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root canal. *Clay* appears to be non-analogous art in the field of nasal sprays, more particularly, a nasal delivered composition for providing anesthesia. *Clay* neither teaches a method in which a disinfecting composition is placed in a root canal, nor is the nasal delivered anesthetic composition of *Clay* a disinfectant suitable for use in a root canal.

Lee discloses a dental training device in which conductive media 20 and 22 are placed *outside* the tooth (see Figs. 2 and 3; ¶¶ [0030] – [0034]). Even though such materials may contain aqueous sodium hypochlorite (see ¶ [0057]), the sodium hypochlorite is not placed in a tooth to disinfect the root canal but remains outside the tooth. Because neither the nasal spray of *Clay* nor the conductive composition of *Lee* are used to disinfect or clean a root canal, one of skill in the art would not have been motivated to apply these references against the claims of the present application.

Nance, on the other hand, is a classic example of a method that employs a non-viscous liquid sodium hypochlorite solution in a root canal. As discussed in the background section of the present application, such compositions are difficult to apply in a controlled manner, particularly in the upper teeth of a patient, since they can easily run off the tooth onto surrounding oral tissue. Application, page 4, lines 3-14; page 23, lines 7-10. The method of disinfecting a root canal in *Nance* is specifically the type of procedure upon which the present invention attempts to improve.

In view of the foregoing, it is clear that none of *Clay*, *Lee* or *Nance* teach or suggest a method of applying a disinfecting composition to a root canal in a controlled manner in order to protect surround oral tissues. More specifically, none of *Clay*, *Lee* or *Nance*, either alone or in combination, teach or suggest the following act recited in amended claim 1:

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introducing a viscous disinfecting composition into the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal, wherein said viscous disinfecting composition is able to adhere to walls of the root canal so as to enable the disinfecting composition to disinfect the root canal.

(Emphasis shows amendment.) Support for the amendment to claim 1 is found in the application at page 5, lines 2-4 and 15-19; page 6, lines 12-14; page 7, lines 18-21; page 23, line 11-12; page 24, lines 13-14; page 25, lines 4-8; Figure 5 (which shows the disinfecting composition remaining adhered to the root canal, thus permitting the composition to "remain substantially on or within the tooth while disinfecting the root canal").

Because the secondary references fail to teach or suggest a method in which a viscous disinfecting composition is applied to a root canal "in a controlled manner" in order for the composition to "remain substantially on or within the tooth while disinfecting the root canal", the only remaining issue is whether *Hahn* discloses such a method. As will now be shown, *Hahn* discloses no such method.

Hahn primarily teaches the use of an oscillating/vibrating device used to chip away or abrade hard dental tissue from a tooth. As shown in the drawings (e.g., Figures 3, 4, 10 and 12-14), the *Hahn* device works similar to a jack-hammer used to break up concrete, but on a much smaller scale in the mouth of a patient. Fragments of dental tissue are shown in the drawings as specks flying off the tooth. In some embodiments, the tooth abrading device may also include an external nozzle that bathes the oscillating abrading device with an abrading fluid. See Figures 3, 4, 6, 8, 10, 12-14 and 16. The purpose of the abrading fluid is to further abrade the teeth. Col. 7, lines 12-col. 8, line 39.

Because of the uncontrolled manner in which tooth material is removed, and also because the abrading fluid cannot be isolated on or in the tooth, *Hahn* further teaches the use of a

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suctioning device to remove fluid from the patient's mouth when fluid is used in combination with the oscillating mechanical device. Col. 8, lines 4-8. In view of this, *Hahn* would not be understood by one of skill in the art as teaching a method for disinfecting a root canal "in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal" as recited in amended claim 1. As explained above, none of *Clay*, *Lee* or *Nance* teach this either. It therefore follows that the combined teachings of the applied references neither teach nor suggest the method recited in claim 1 as amended.

Claim 20 was alternatively amended to specifically recite a method for disinfecting a root canal using a preferred viscous disinfecting composition comprising "sodium hypochlorite, water, and a gelling agent comprising at least one member selected from the group consisting of fumed silica, fumed aluminum oxide, and carboxypolymethylene". Support for this limitation is found in originally filed claims 4 and 6. As discussed during the examiner interview, none of the cited references teach or suggest the use of a viscous disinfectant solution that includes sodium hypochlorite, water and one or more of fumed silica, fumed aluminum oxide, or carboxypolymethylene.

The only reference alleged by the Office Action to mention fumed silica and fumed aluminum oxide is *Hahn*. As discussed during the examiner interview, however, *Hahn* does not describe the use of either fumed silica or fumed aluminum oxide. Instead, *Hahn* only teaches the use of "alumina particles" as a type of abrasive particle used in connection with the oscillating abrasion device. Col. 7, line 16. Such particles are further described as requiring "continuous stirring or flowing gas" in order to keep them suspended in the liquid. Col. 7, lines 28-30. That means the "alumina particles" are not colloidal and therefore do not act as a "gelling agent". They are clearly not "fumed aluminum oxide". Similarly, whereas *Hahn* describes the use of

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"silicates" or unnamed particles that are "silanized", *Hahn* likewise fails to teach the use of "fumed silica" or any other type of silica as a "gelling agent". The terms "fumed silica" and "fumed aluminum oxide" are terms well-known in the art to describe sub-micron sized particles. See Exhibit A (fumed silica described as having particle size ranging from 0.007 to 0.05 micron) and Exhibit B (fumed alumina described as a "nanoparticle"). Applicants have discovered that fumed silica and fumed aluminum oxide are useful in forming viscous disinfecting compositions. None of the cited art teaches or suggests their use in a disinfecting composition that includes water and sodium hypochlorite.

Hahn likewise fails to teach the use of carboxypolymethylene. As discussed during the examiner interview, one of skill in the art would not have been motivated to combine *Clay* with *Hahn*. *Clay* does not disclose a disinfectant composition suitable for use in disinfecting a root canal. Instead, *Clay* discloses a nasal spray for delivery of an anesthetic deep within a person's nasal cavity. See Figures 6 and 7. *Clay* therefore constitutes nonanalogous art to both the claimed method as well as *Hahn*. There is simply no technological nexus between the nasal spray of *Clay* and a root canal disinfecting composition that would have motivated one of skill in the art to modify the *Hahn* composition to include carboxypolymethylene. Accordingly, Applicants submit that the combined teachings of the cited art neither teach nor suggest the method claim 20.

Claim 25 as amended recites the use of a viscous disinfecting composition comprising sodium hypochlorite, water, and "at least one of fumed silica or fumed aluminum oxide in an amount in a range of about 1% to about 10% by weight". As discussed above, none of the cited references teach or suggest the use of fumed silica or fumed aluminum oxide as a gelling agent within a viscous disinfecting composition, let alone within the specific range recited in claim 25.

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In fact, the Office Action fails to identify any teaching or suggestion in the art for the claimed range "of about 1% to about 10% by weight" for the fumed silica in original claim 25.

In conclusion, Applicants submit that the claims as now amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or that may be overcome by examiner amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 4th day of April 2005.

Respectfully submitted,



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